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JC971 U.S. PTO 11/27/00

UTILITY PATENT APPLICATION TRANSMITTAL (for nonprovisional applications under 37 C.F.R. § 1.53(b))	Attorney Docket No.	PHSC.70080
	Express Mail No.	EL375134485US

JC748 U.S. PTO 09/723064 11/27/00

TO: Box Patent Application
Commissioner for Patents
Washington, D.C. 20231

Inventor(s): RICHARD MIHALIK

Title: AN ANTIBIOTIC/ANALGESIC FORMULATION AND A METHOD OF MAKING THIS FORMULATION

Enclosed are:

- [X] 14 pages of specification including abstract
- [ ] sheet(s) of drawings
- [X] an assignment of the invention to: Phoenix Scientific, Inc.
- [X] Declaration/Oath of Inventor(s): [X] Newly executed [ ] Copied from a prior application (for contin/div)
- [ ] Incorporation by Reference: the entire disclosure of the prior application, from which the copy or copies of the oath or declaration is supplied, is considered to be part of the disclosure of the accompanying application and is hereby incorporated by reference therein.
- [X] a small entity statement is enclosed.
- [ ] a small entity statement was filed in prior application; status still proper and desired.
- [ ] Information Disclosure Statement/PTO-1449/Copies of IDS citations.
- [ ] other:

If a Continuing Application: Check appropriate box, and supply the requisite information below:

[ ] Continuation [ ] Divisional [ ] Continuation-in-Part (CIP) of prior application No.

Prior application information:	Examiner:	Group Art Unit:

CLAIMS AS FILED

	NUMBER FILED	NUMBER EXTRA	RATE	FEE
BASIC FEE			$710	$ 710
TOTAL CLAIMS	21 - 20 =	1	X $ 18	$ 18
INDEPENDENT CLAIMS	3 - 3 =	0	X $ 80	$ 0
MULTIPLE DEPENDENT CLAIM PRESENT			$270	$
* Number extra must be zero or larger			TOTAL	$728
If applicant has small entity status under 37 CFR 1.9 and 1.27, then divide total fee by 2, and enter amount here.			SMALL ENTITY TOTAL	$364

- [X] A check in the amount of $364.00 to cover the filing fee is enclosed.
- [X] Commissioner is hereby authorized to charge/credit Deposit Acct. No. 19-2112 as described below Enclosed is a duplicate of this sheet.
  - [ ] Charge the amount of $_____ as filing fee.
  - [X] Credit any overpayment.
  - [X] Charge any additional filing fees required under 37 CFR 1.16 and 1.17.

Susan J. Wharton
Signature

11/27/00
Date

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Richard Mihalik	)	Attorney Docket No. PHSC.70080
	)	
AN ANTIBIOTIC/ANALGESIC	)	
FORMULATION AND A METHOD OF	)	
MAKING THIS FORMULATION	)	

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(f) and 1.27(c)) SMALL BUSINESS CONCERN

I hereby declare that I am an official of the small business concern empowered to act on behalf of the concern identified below:

Name of Concern:	Phoenix Scientific, Inc.
Address of Concern:	3915 South 48th Street Terrace
	St. Joseph, Missouri 64506-0457

I hereby declare that the above-identified small business concern qualifies as a small business concern as defined in 13 CFR 121.3-18, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees under section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time, or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention, entitled AN ANTIBIOTIC/ANALGESIC FORMULATION AND A METHOD OF MAKING THIS FORMULATION by inventor Richard Mihalik described in the specification filed herewith.

If the rights held by the above-identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below and no rights to the invention are held by any person, other than the inventor, who could not qualify as a small business concern under 37 CFR 1.9(d) or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

Name: _____

Address: _____

[ ] individual [ ] small business concern
[ ] nonprofit organization

Name: _____

Address: _____

[ ] individual [ ] small business concern
[ ] nonprofit organization

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Name of Person Signing: Kevin M. Schinze
Title of Person Other than Owner: President/CEO
Address of Person Signing: Phoenix Scientific, Inc.
3915 South 48th Street Terrace
St. Joseph, Missouri 64506-0457

Signature 11/27/2020 Date

EL375134485US

AN ANTIBIOTIC/ANALGESIC FORMULATION AND A METHOD OF MAKING THIS FORMULATION

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

Not Applicable.

CROSS-REFERENCE TO RELATED APPLICATIONS

Not Applicable.

BACKGROUND OF THE INVENTION

The present invention relates to a formulation for fighting infection, counteracting inflamation, and reducing fever. More specifically, the present invention relates to an antibiotic/analgesic formulation for use in veterinary applications.

Antibiotics and analgesics are currently available in separate formulations, but they are frequently administered at about the same time. One disadvantage with formulations currently available is that antibiotics and analgesics must be administered separately. As a result, two dosages must be administered each time both are administered.

In order to overcome this disadvantage, formulations that include both an antibiotic and an analgesic are needed. These formulations should be usable in pour-on or injectable forms.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide a formulation that contains both an antibiotic and an analgesic so that both can be administered together.

It is a further object of the present invention to provide a method of making an antibiotic/analgesic formulation.

According to the present invention, the foregoing and other objects are achieved by a pour-on or an injectable antibiotic/analgesic formulation that includes a mixture of an antibiotic, an analgesic, and at least one solvent.

Additional objects, advantages and novel features of the invention will be set forth in part in the description which follows, and in part will become apparent to those skilled in the art upon examination of the following, or may be learned from the practice of the invention. The objects and advantages of the invention may be realized and attained by means of the instrumentalities and combinations particularly pointed out in the appended claims.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The formulation of the present invention is an effective pour-on or injectable formulation for fighting infection, counteracting inflammation, and reducing fever. This formulation includes an antibiotic, an analgesic, and at least one solvent.

The antibiotic in the formulation of the present invention functions to suppress or destroy microorganisms and acts to treat and prevent diseases. The antibiotic that may be used in this formulation includes, but is not limited to, florfenicol, any salt of oxytetracycline including oxytetracycline dihydrate, chlortetracycline, tetracycline, gentamicin, chloramphenicol, tylosin, cephalosporins, or combinations thereof.

The analgesic in the formulation of the present invention acts as an anti-inflammatory and an antipyretic. It counteracts inflamation, reduces fever, and relieves pain. It may be in a steroidal or non-steroidal form. The analgesic that may be used in this formulation includes, but is not limited to, dexamethasone, flunixin meglumine, or combinations thereof.

The solvent that may be used in the formulation of the present invention may include, but is not limited to, N-methyl-2-pyrrolidone, glycerol formal, 2-pyrrolidone, polyethylene glycol, propylene glycol, glycerine, N,5-dimethyl-2-pyrrolidone, 3,3-dimethyl-2-pyrrolidone, N-ethyl-2-pyrrolidone, N-ethyloxy-2-pyrrolidone, N-ethylene-2-pyrrolidone, 1-pyrrolidone, water, diethylene glycol monobutyl ether, benzyl benzoate, isopropyl alcohol, xylenes, or combinations thereof. When florfenicol is used as the antibiotic, however, water should not be used as the only solvent.

While an antibiotic, analgesic, and a solvent are the only components necessary in the formulation of the present invention, a number of optional components may be added to enhance various properties of the formulation. Such optional components may include an antioxidant, a solubilizing agent, a complexing agent, a preservative, a pH adjusting agent, a buffer, or combinations thereof.

Examples of antioxidants that may be used include, but are not limited to, edetate disodium, sodium metabisulfite, sodium formaldehyde sulfoxylate, vitamin E acetate, vitamin C, vitamin B_{12}, or combinations thereof. Preferably, sodium formaldehydesulfoxylate is included in the formulation when any salt of oxytetracycline is part of the formulation.

The solubilizing agent for the formulation of the present invention may be, but is not limited to, cross-linked polypyrrolidone such as povidone C-15 (having 15 monomer units), magnesium oxide, calcium oxide, or combinations thereof. Preferably, a solubilizing agent is included in the formulation when any salt of oxytetracycline is part of the formulation.

Complexing agents are a type of solubilizing agent and may be present as the solubilizing agents listed above or in addition to the solubilizing agents. Examples of complexing agents that may be used include, but are not limited to, calcium oxide, calcium chloride, magnesium oxide, borate salts,

any soluble polymer of 2-pyrrolidone such as cross-linked polypyrrolidone or polyvinyl pyrrolidone, or combinations thereof.

Examples of preservatives that may be used include, but are not limited to, benzyl alcohol, ethyl alcohol, parabens such as methyl-, ethyl-, propyl-, or butylparaben, chlorobutanol, sodium benzoate, benzoic acid, myristyl-gamma-picolinium chloride, benzalkonium chloride, benzethonium chloride, cetylpyridinium chloride, chlorocresol, cresol, dehydroacetic acid, methylparaben sodium, phenol, phenylethyl alcohol, potassium benzoate, potassium sorbate, propylparaben sodium, sodium dehydroacetate, sodium propionate, sorbic acid, thymol, or combinations thereof.

The pH adjusting agent may be hydrochloric acid. The buffer may be monoethanolamine.

The antibiotic desirably is present in the formulation in an amount effective to suppress or destroy unwanted microorganisms. The total amount of antibiotic used in the formulation of the present invention may be about 1-60% weight/volume (w/v). Preferably, the formulation of the present invention includes about 15-40% w/v antibiotic. Most preferably, the formulation includes about 30-40% w/v antibiotic. If oxytetracycline dihydrate is used as the antibiotic, then an antioxidant such as sodium formaldehyde sulfoxylate should be used therewith.

The analgesic desirably is present in the formulation in an amount effective to counteract inflammation and reduce fever. If flunixin meglumine is used as the analgesic, then it should be present in the formulation of the present invention in an amount of about 2-15% w/v. Preferably, if flunixin meglumine is used, the formulation has about 5-12% w/v flunixin meglumine. Most preferably, about 8-10% w/v of flunixin meglumine is used. The amount of flunixin in the flunixin meglumine should be about 1-5% w/v. Alternatively, dexamethasone may be used as the analgesic agent, and in that case,

about 0.01-5% w/v is used. Preferably, about 0.03-1% dexamethasone is used, and most preferably, about 0.05-0.1% dexamethasone is used.

The amount of solvent used in the formulation of the present invention should be sufficient to dissolve all of the components of the formulation. The solvent should be present in an amount between about 20-95% w/v depending on the concentration of antibiotic and analgesic present in the formulation.

It is desirable to add a preservative to the formulation of the present invention. The preservative functions as an antibacterial or antimicrobial agent. The total amount of preservative in this formulation is about 0-15% w/v. Preferably, a preservative is present in an amount of about 0.01-10% w/v. Most preferably, a preservative is about 0.5-3% w/v of the formulation.

If an antioxidant is present in the formulation, it is about 0.005-3% w/v of the formulation. Preferably, it is about 0.1-1% w/v of the formulation.

If a cross-linked polypyrrolidone is used as a solubilizing or complexing agent in the formulation, it is present as about 1-10% w/v of the formulation. If magnesium or calcium containing components are present in the formulation, each is about 1-20% w/v of the formulation. If pyrrolidone containing components are present, they are about 5-90% w/v of the formulation, and preferably, they are about 30-50% of the formulation.

The antibiotic/analgesic formulation of the present invention may be administered as a pour-on product or as a parenteral formulation. Preferably, it is administered as a parenteral injection formulation to cats, dogs, horses, cattle, pigs, sheep, or poultry. Typically, the formulation is administered to animals in a dosage of 0.5-200 mg/kg of animal depending upon the severity of the pain, inflamation, fever and/or infection and depending upon the type of animal being treated.

Preferably, it is administered in a dosage of 1-150 mg/kg. If water is used in the formulation, the pH of the formulation should be between about 4 and 10. Preferably, the formulation has a pH between about 6 and 8.

The following are examples of various antibiotic/analgesic formulations of the present invention and methods of making these formulations. These methods are within the scope of this invention. These examples are not meant in anyway to limit the scope of this invention.

Example 1

N-methyl-2-pyrrolidone was added to a vessel. Agitation began. With continued agitation, a quantity of florfenicol amounting to 30% w/v of the final formulation was added to the solvent and mixed with the solvent until it dissolved. A quantity of flunixin meglumine amounting to 4.15% w/v of the final formulation was then added and mixed into the solution. This flunixin meglumine was 2.5% w/v flunixin. Next, benzyl alcohol was added in a quantity amounting to 2% w/v of the final formulation, and the resulting solution was mixed until all components were adequately dissolved. With continued agitation, a supplemental amount of N-methyl-2-pyrrolidone was added in an amount sufficient to completely dissolve any remaining undissolved components. The total amount of N-methyl-2-pyrrolidone added made up the balance of the formulation. The resulting formulation can be used for parenterally or as a pour-on.

Example 2

N-methyl-2-pyrrolidone was added to a vessel. Agitation began. With continued agitation, a quantity of florfenicol amounting to 60% w/v of the final formulation was added to the solvent and mixed with the solvent until it dissolved. A quantity of flunixin meglumine amounting to 8.29% w/v of the final formulation was then added and mixed into the solution. This flunixin

meglumine was 5.00% w/v flunixin. Next, benzyl alcohol was added in a quantity amounting to 2% w/v of the final formulation, and the resulting solution was mixed until all components were adequately dissolved. With continued agitation, a supplemental amount of N-methyl-2-pyrrolidone was added in an amount sufficient to completely dissolve any remaining undissolved components. The total amount of N-methyl-2-pyrrolidone added made up the balance of the formulation. The resulting formulation can be used parenterally.

Example 3

N-methyl-2-pyrrolidone was added to a vessel. Agitation began. With continued agitation, a quantity of florfenicol amounting to 60% w/v of the final formulation was added to the solvent and mixed with the solvent until it dissolved. A quantity of flunixin meglumine amounting to 8.29% w/v of the final formulation was then added and mixed into the solution. This flunixin meglumine was 5.00% w/v flunixin. Next, benzyl alcohol was added in a quantity amounting to 10% w/v of the final formulation, and the resulting solution was mixed until all components were adequately dissolved. With continued agitation, a supplemental amount of N-methyl-2-pyrrolidone was added in an amount sufficient to completely dissolve any remaining undissolved components. The total amount of N-methyl-2-pyrrolidone added made up the balance of the formulation. The resulting formulation can be used parenterally.

Example 4

N-methyl-2-pyrrolidone was added to a vessel. Agitation began. With continued agitation, a quantity of florfenicol amounting to 50% w/v of the final formulation was added to the solvent and mixed with the solvent until it dissolved. A quantity of flunixin meglumine amounting to 6.91% w/v of the final formulation was then added and mixed into the solution. This flunixin

meglumine was 4.17% w/v flunixin. Next, benzyl alcohol was added in a quantity amounting to 8.33% w/v of the final formulation, and the resulting solution was mixed until all components were adequately dissolved. With continued agitation, glycerol formal amounting to 16.6% w/v of the final formulation was added to the solution. With continued agitation, a supplemental amount of N-methyl-2-pyrrolidone was added in an amount sufficient to completely dissolve any remaining undissolved components. The total amount of N-methyl-2-pyrrolidone added made up the balance of the formulation. The resulting formulation can be used parenterally.

Example 5

Water was added to a vessel. Agitation began. With continued agitation, a quantity of flunixin meglumine amounting to 2.77% w/v of the final formulation was added to the water and mixed with the water until it dissolved. This flunixin meglumine was 1.67% w/v flunixin. Next, 2-pyrrolidone was added in a quantity amounting to 40% w/v of the final formulation. Povidone C-15 cross-linked polypyrrolidone (having 15 monomer units) was then added in a quantity amounting to 5.00% w/v of a final formulation. Following this, magnesium oxide was added in a quantity amounting to 1.80% w/v of the final formulation. Sodium formaldehyde sulfoxylate was then added in a quantity amounting to 0.20% w/v of the final formulation. Next, monoethanolamine was added in a quantity amounting to 0.3% w/v of the final formulation. A quantity of oxytetracycline dihydrate amounting to 24.04% w/v of the final formulation was then added and mixed into the solution. This oxytetracycline dihydrate was 20.0% w/v oxytetracycline. The pH of the formulation was adjusted by adding hydrochloric acid in the amount of 0.022% w/v of the final formulation, and the resulting solution was mixed until all components were adequately dissolved. With continued agitation, a supplemental amount of water was added in an amount sufficient to completely dissolve any remaining undissolved

components. The total amount of water added made up the balance of the formulation. The resulting formulation can be used parenterally.

Example 6

Water was added to a vessel. Agitation began. With continued agitation, a quantity of gentamicin base as gentamicin sulfate amounting to 8.50% w/v of the final formulation was added to the water and mixed with the water until it dissolved. A quantity of dexamethasone amounting to 0.03% w/v of the final formulation was then added and mixed into the solution. Next, polyethylene glycol 400 (having an average molecular weight of 400 as defined in The Merck Index, 12th edition, 1996) was added to the formulation in a quantity amounting to 7.5% w/v of the final formulation. Next, sodium metabisulfite was added in a quantity amounting to 0.272% w/v of the final formulation. Following this, benzyl alcohol was added in a quantity amounting to 0.135% w/v of the final formulation. Next, methylparaben was added in a quantity amounting to 0.180% w/v of the final formulation, and then propylparaben was added in a quantity amounting to 0.020% w/v of the final formulation. Ethyl alcohol (95%) was then added in a quantity amounting to 0.75% w/v of the final formulation. Next, edetate disodium was added in a quantity amounting to 0.0085% w/v of the final formulation, and the resulting solution was mixed until all components were adequately dissolved. With continued agitation, a supplemental amount of water was added in amount sufficient to completely dissolve any remaining undissolved components. The total amount of water added made up the balance of the formulation. The resulting formulation can be used parenterally.

Example 7

N-methyl-2-pyrrolidone was added to a vessel. Agitation began. With continued agitation, a quantity of florfenicol amounting to 30% w/v of the final formulation was added to the

solvent and mixed with the solvent until it dissolved. A quantity of dexamethasone amounting to 0.067% w/v of the final formulation was then added and mixed into the solution. Benzyl alcohol amounting to 2.3% w/v of the final formulation was then added to the solution. Next, polyethylene glycol 400 was added in a quantity amounting to 16.75% w/v of the final formulation. Methylparaben amounting to 0.0603% w/v of the final formulation and propylparaben amounting to 0.0067% w/v of the final formulation were then added to the solution. Following this, ethyl alcohol was added in a quantity amounting to 1.675% w/v of the final formulation. Water was then added in a quantity amounting to 14.6% w/v of the final formulation, and the resulting solution was mixed until all components were adequately dissolved. With continued agitation, a supplemental amount of N-methyl-2-pyrrolidone was added in an amount sufficient to completely dissolve any remaining undissolved components. The total amount of N-methyl-2-pyrrolidone added made up the balance of the formulation. The resulting formulation can be used parenterally or as a pour-on.

From the foregoing, it will be seen that this invention is one that is well adapted to attain all the ends and objects herein above set forth together with other advantages which are obvious and inherent to the formulation. It will be understood that certain features and subcombinations are of utility and may be employed without reference to other features and subcombinations. This is contemplated by and is within the scope of the claims. Since many possible embodiments may be made of the invention without departing from the scope thereof, it is to be understood that all matter herein set forth is to be interpreted as illustrative and not in a limiting sense.

I claim:

1. An analgesic/antibiotic formulation for veterinary use, comprising a mixture of:

at least one antibiotic;

at least one analgesic; and

at least one solvent, wherein said antibiotic and said analgesic are dissolved in said solvent to form a mixture.

2. The formulation of claim 1, wherein said antibiotic is selected from the group consisting of florfenicol, any salt of oxytetracycline, chlortetracycline, tetracycline, gentamicin, chloramphenicol, tylosins, cephlasporins, and combinations thereof.

3. The formulation of claim 1, wherein said analgesic is selected from the group consisting of flunixin meglumine, dexamethasone, and combinations thereof.

4. The formulation of claim 1, wherein said formulation is comprised of florfenicol and flunixin meglumine.

5. The formulation of claim 1, wherein said formulation is comprised of florfenicol and dexamethasone.

6. The formulation of claim 1, wherein said solvent is selected from the group consisting of N-methyl-2-pyrrolidone, 2-pyrrolidone, N-5-dimethyl-2-pyrrolidone, 3-3-dimethyl-2-pyrrolidone, N-ethyl-2-pyrrolidone, N-ethyloxy-2-pyrrolidone, N-ethylene-2-pyrrolidone, 1-pyrrolidone, glycerol formal, propylene glycol, polyethylene glycol, glycerine, water, diethylene glycol monobutyl ether, benzyl benzoate, isopropyl alcohol, xylenes, and combinations thereof.

7. The formulation of claim 1, further comprising:

a preservative.

8. The formulation of claim 7, wherein said preservative is selected from the group consisting of benzyl alcohol, ethyl alcohol, parabens, chlorobutanol, sodium benzoate, benzoic acid, myristyl-gamma-picolinium chloride, benzalkonium chloride, benzethonium choloride, cetylpyridinium chloride, chlorocresol, cresol, dehydroacetic acid, methylparaben sodium, phenol, phenylethyl alcohol, potassium benzoate, potassium sorbate, propylparaben sodium, sodium dehydroacetate, sodium propionate, sorbic acid, thymol, and combinations thereof.

9. The formulation of claim 1, further comprising:

one or more components selected from the group consisting of an antioxidant, a solubilizing agent, a buffer, and a complexing agent.

10. The formulation of claim 9, wherein said formulation is comprised of an antioxidant selected from the group consisting of edetate disodium, sodium metabisulfite, sodium formaldehyde sulfoxylate, vitamin E acetate, vitamin C, vitamin B_{12}, and combinations thereof.

11. The formulation of claim 10, wherein said antioxidant is sodium formaldehyde sulfoxylate and said antibiotic is oxytetracycline dihydrate.

12. The formulation of claim 1, wherein said formulation is comprised of a salt of oxytetracycline, sodium formaldehydesulfoxylate, and a solubilizing agent.

13. The formulation of claim 1, wherein said formulation is comprised of about 5-60% w/v antibiotic, about 0.01-15% w/v analagesic, and about 20-95% w/v solvent.

14. The formulation of claim 1, wherein said formulation is comprised of about 15-40% w/v antibiotic, about 0.03-12% analgesic, and about 20-85% w/v solvent.

15. The formulation of claim 1, wherein said formulation has a pH between about 4 and 10.

16. A method of making an antibiotic/analgesic formulation, comprising:

mixing an antibiotic with a solvent to form a solution;

adding an analgesic to said solution; and

mixing said solution to form an antibiotic/analgesic formulation.

17. The method of claim 16, further comprising:

adding to said formulation one or more components selected from the group consisting of a preservative, an antioxidant, a complexing agent, a pH adjusting agent, a buffer, and a solubilizing agent.

18. A method for treating an animal, comprising:

administering to an animal in need thereof a formulation comprising a mixture of an antibiotic, an analgesic, and a solvent.

19. The method of claim 18, wherein said formulation is a parenterally injectable formulation and is injected through the skin of said animal.

20. The method of claim 19, wherein said animal is a cat, dog, horse, cow, pig, sheep, or poultry.

21. The method of claim 19, wherein said formulation is administer in a dosage of about 0.5-200 mg/kg of animal.

ABSTRACT

A formulation that includes a mixture of at least one antibiotic, at least one analgesic, and at least one solvent is provided. The antibiotic and the analgesic are dissolved in the solvent to form a formulation that is suitable for veterinary applications. This formulation can be administered to animals as a pour-on or an injectable formulation.

DECLARATION FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled AN ANTIBIOTIC/ANALGESIC FORMULATION AND A METHOD OF MAKING THIS FORMULATION the specification of which is attached hereto.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, 1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, § 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed: NONE.

I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application: NONE.

I hereby appoint the following attorneys to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith and to file and prosecute any corresponding foreign applications, including any international applications William B. Kircher, Reg. No. 22,481; James H. Marsh, Jr., Reg. No. 24,533; J. David Wharton, Reg. No. 25,717; Joseph B. Bowman, Reg. No. 25,807; Richard R. Johnson, Reg. No. 27,452; Walter R. Brookhart, Reg. No. 29,518; James H. Riley, II, Reg. No. 31,131; Joan Optican Herman, Reg. No. 31,968; Michael B. Hurd, Reg. No. 32,241; Devon A. Rolf, Reg. No. 35,337; Michael J. Gross, Reg. No. 35,528; William P. Jensen, Reg. No. 36,833; Daniel W. Shinn, Reg. No. 40,810; B. Trent Webb, Reg. No. 40,865; Susan J. Wharton, Reg. No. 41,524; Scott B. Strohm, Reg. No. 42,172; Clinton G. Newton, Reg. No. 42,930. Address all correspondence to: Susan J. Wharton, SHOOK, HARDY & BACON L.L.P., One Kansas City Place, 1200 Main Street, Kansas City, Missouri 64105-2118 , telephone number (816) 474-6550.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Inventor's signature _____ 11/27/00

Richard Mihalik — Date

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